

IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

1. (currently amended) An oral vaccine comprising a recombinant lactic acid bacterium which expresses a heterologous antigen intracellularly and/or on the surface of the bacterium, wherein the bacterium is *Lactobacillus plantarum* and which elicits an immune response against the heterologous antigen in a subject to whom the vaccine is administered orally.
2. (previously presented) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises an expression vector which expresses the heterologous antigen intracellularly.
3. (currently amended) The vaccine according to claim 1 wherein the heterologous antigen induces an immune response against a pathogenic microorganism in said subject to whom the vaccine is administered orally.
4. (currently amended) The vaccine according to claim 1 wherein the heterologous antigen induces an immune response against a pathogenic microorganism colonising the gastrointestinal tract in said subject to whom the vaccine is administered orally.
5. (currently amended) The vaccine according to claim 1 wherein the heterologous antigen induces an immune response against a pathogenic microorganism selected from the group consisting of herpes virus, rubella virus, influenza virus, mumps virus, measles virus, poliomyelitis virus, rotavirus, respiratory syncytial virus, Campylobacter species, Chlamydial organisms, species of the genus *Cryptosporidium*, cytomegalovirus, human ~~immunodeficiency~~ immunodeficiency virus, *Actinomyces* species, *Entamoeba histolytica*, arenaviruses, arboviruses, *Clostridium botulinum*, species of the genus *Candida*, *Vibrio cholerae*, *Cryptococcus neoformans*, Enterohemorrhagic strains of *E. coli* (EHEC), O157:H7, O26:H11, O111:H8 and

O104:H21, Enterotoxigenic strains of *E. coli* (ETEC), strains of *E. coli* shown to possess enteroinvasiveness (EIEC), Enteropathogenic strains of *E. coli* (EPEC), Enteroaggregative strains of *E. coli* (EaggEC), Difficulty adhering strains of *E. coli* (DAEC), filoviridae, parvovirus, *Filarioidea*, *Staphylococcus aureus*, species of the genus *Clostridium perfringens*, *Helicobacter pylori*, Caliciviruses, *Giardia lamblia*, *Neisseria gonorrhoeae*, hantaviruses, hepatitis virus types A, B, C, D, and E, *Legionellae* strains, *Mycobacterium leprae*, *Listeria monocytogenes*, *Borrelia burgdorferi*, *Pseudomonas pseudomallei*, Epstein Barr virus, *Onchocerca volvulus*, Poxvirus, *Bordetella pertussis*, *Yersinia pestis*, *Coxiella burnetii*, rabies virus, *Treponema pallidum*, *Mycobacterium tuberculosis*, *Salmonella typhi*, a eukaryotic parasite causing malaria, *Pneumocystis carinii*, an agent causing toxoplasmosis, and any combination thereof in said subject to whom the vaccine is administered orally.

6. (currently amended) The vaccine according to claim 1 which elicits a protective immune response against a pathogenic microorganism selected from the group consisting of rotavirus, respiratory syncytial virus, *Mycobacterium tuberculosis*, human immunodeficiency virus, *E. coli*, *Vibrio cholerae*, streptococci and chlamydia in said subject to whom the vaccine is administered orally.

7. (previously presented) The vaccine according to claim 1 wherein the heterologous antigen is a viral or bacterial antigen.

8. (previously presented) The vaccine according to claim 1 wherein the heterologous antigen is a human allergen or the heterologous antigen is specific for tetanus.

9. (currently amended) The vaccine according to claim 1 which induces a protective immune response against a pathogenic microorganism that the heterologous antigen is from in said subject to whom the vaccine is administered orally.

10. (previously presented) The vaccine according to claim 1 formulated as a single dose vaccine.

Claim 11 (canceled)

12. (previously presented) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises a homologous expression or secretion signal.

13. (currently amended) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* exhibits a persistence exceeding 5 days in said subject to whom the vaccine is orally administered.

Claim 14 (canceled)

15. (previously presented) The vaccine according to claim 1 formulated for oral administration to a human.

16. (previously presented) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* is recombinant *Lactobacillus plantarum* 256.

17. (previously presented) The vaccine according to claim 1 wherein the vaccine comprises at least one adjuvant or a pharmacologically acceptable carrier.

18. (previously presented) A recombinant *Lactobacillus plantarum* bacterium which expresses a heterologous antigen intracellularly and/or on the surface of the bacterium, wherein the bacterium elicits an immune response against the heterologous antigen in a subject to whom the vaccine is administered orally.

Claim 19 (canceled)

20. (previously presented) A *Lactobacillus plantarum* bacterium from a non-human foodstuff or of non-human origin which expresses a heterologous antigen so that the bacterium elicits an immune response in an individual when administered orally.

21. (previously presented) The bacterium according to claim 20 wherein the bacterium is foreign to said individual.

22. (previously presented) A *Lactobacillus plantarum* bacterium which has been modified to express a heterologous antigen intracellularly and/or on the cell surface, to elicit an immune response in an individual when administered orally and which can persist in the gastrointestinal tract of said individual for at least 7 days.

23. (previously presented) The recombinant *Lactobacillus plantarum* according to claim 18 for use in a vaccine.

24. (previously presented) An expression vector suitable for intracellular expression or exposure of a heterologous antigen, the expression vector being capable of providing expression in a *Lactobacillus plantarum* of the heterologous antigen under conditions existing in the gastrointestinal tract.

25. (previously presented) The bacterium according to claim 19 for use in a method of prophylaxis or treatment of the human or animal body.

26. (withdrawn) A method of using a *Lactobacillus* bacterium which has been modified to express a heterologous antigen intracellularly and/or on the cell surface comprising administration of a vaccine to an individual for whom the unmodified *L. plantarum* is foreign.

27. (withdrawn) The method according to claim 26 wherein the unmodified *Lactobacillus* is *L. plantarum*, is not found in humans (the strain is endogenous) or is not present in the gastrointestinal tract or mucosa of mammals.

28. (withdrawn) A method of using a bacterium according to claim 19 comprising administration of a vaccine comprising said bacterium.

29. (withdrawn) The method according to claim 28 wherein the vaccine is adapted for oral administration and/or elicits an immune response on administration.

30. (withdrawn) The method according to claim 26 for treating or preventing tetanus.

31. (previously presented) The vaccine according to claim 3 wherein the heterologous antigen is specific for a pathogenic microorganism entering the body mucosally via the oral route.

32. (previously presented) The vaccine according to claim 15 wherein the human is selected from the group consisting of an infant, an immunocompromised person, an elderly person, a normally healthy infant, a normally healthy child, and a normally healthy adult.

33. (previously presented) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises an expression vector which expresses the heterologous antigen on the cell surface.

34. (previously presented) The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises an expression vector which expresses the heterologous antigen intracellularly and on the cell surface.

35. (previously presented) The vaccine according to claim 3 wherein said heterologous antigen is a heterologous antigen specific for a mucosa colonising pathogenic microorganism or a pathogenic microorganism entering the body via the mucosa.

36. (previously presented) The vaccine of claim 7 wherein the heterologous antigens is a gp160 envelope protein of the HIV virus, a surface glycoprotein of a *Leishmania* parasite, Shiga-like toxin, *Shigella* lipopolysaccharide antigen, *Escherichia coli* fimbrial antigen, a Coli Fimbrial Antigen (CFA) of an enterotoxigenic *Escherichia coli* strain, anthrax toxin, pertussis toxin, or tetanus toxin.

37. (previously presented) The vaccine according to claim 12 wherein said homologous expression or secretion signal is an expression vector for *Lactobacilli*.

38. (previously presented) The vaccine according to claim 37 wherein said expression vector is an expression vector for *Lactobacillus plantarum*.

39. (previously presented) The vaccine according to claim 13 wherein said recombinant *Lactobacillus plantarum* strain exhibits a persistence in the vaccinated individual exceeding 9 days.

40. (previously presented) The vaccine according to claim 39 wherein said strain exhibits a persistence of more than 15 days in the vaccinated individual.

41. (previously presented) The vaccine according to claim 40 wherein said strain exhibits a persistence of more than 20 days in the vaccinated individual.

42. (previously presented) The recombinant *Lactobacillus plantarum* according to claim 18 which is a recombinant strain of *Lactobacillus plantarum* 256.

43. (previously presented) The bacterium according to claim 20 wherein the bacterium is not present in the gastrointestinal tract or mucosa of humans.

44. (previously presented) The bacterium according to claim 20 wherein the antigen is expressed intracellularly.

45. (previously presented) The bacterium according to claim 20 wherein the antigen is expressed on the cell surface.

46. (previously presented) The bacterium according to claim 21 wherein the antigen is an immunogen.